Fukuda Denshi Co, Ltd
39-4 Hongo 3-chome,
Bunkyo-ku, Tokyo, Japan

FUKUDA DENSHI

K110920

Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c)

APR - 8 2011

1. Submitter Information

a. Submitter:	Fukuda Denshi Co. Ltd. 39-4 Hongo 3-chome, Bunkyo-ku Tokyo 113-8420 Japan
b. Contact Person:	Mr. Loran Van Noy Fukuda Denshi USA INC. 17725 N.E. 65th Street Bldg. C Redmond, WA 98052-4911 Phone:425-881-7737 Fax: 425-869-2018
c. Date Prepared:	10 February 2011

2. Name of device

a. Trade name:	UF-760AG
b. Common name:	Medical Diagnostic Ultrasound Imaging System and transducers
c. Classification:	Class II
d. Classification name:	Ultrasonic Pulsed Doppler Imaging System 21 CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System 21 CFR 892.1560 90-IYO Diagnostic Ultrasonic Transducer 21 CFR 892.1570 90-ITX

3. Equivalent Legally-Marketed Devices:

Fukuda Denshi UF-870AG (K081919)

GE, Voluson 730 (K003525, K032620 and K041688)

The technological characteristics of the predicate device are the same as those of the new device.

4. Description

The UF-760AG ultrasound instrument is intended to perform the following diagnostic ultrasound investigations: Imaging (B-mode, 3D/4D), Time motion (M-mode), Pulsed wave Doppler (PW Doppler), Continuous wave Doppler (CW Doppler), Color Flow Mapping (CFM) and Color Time Motion (CM).

The submission also includes the transducers necessary for these procedures.

The system is a portable unit approximately 14.5" wide, 14.4" deep and 3.9" high equipped with a keyboard control panel, a 15" TFT screen, assorted transducers and image storage or hard-copy devices.

5. Intended use

Diagnostic ultrasound investigations: Imaging (B-mode, 3D/4D), Time motion (M-mode), Pulsed wave Doppler (PW Doppler), Continuous wave Doppler (CW Doppler), Color Flow Mapping (CFM) and Color Time Motion (CM).

6. Performance Data

a. Non-clinical tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 60601-1-4
- IEC 60601-2-37
- IEC 62304
- ISO 10993-1
- ISO 14971
- AIUM AOMS-2004
- AIUM RTD1-2004

Cleared patient contact materials, electrical and mechanical safety are unchanged.

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirement Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety Testing (Verification)

b. Clinical tests: Since the UF-760AG uses the same technology and principles as existing devices, clinical tests are not required.

c. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO13485:2003 quality system standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Fukuda Denshi that the UF-760AG is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Fukuda Denshi Co., Ltd
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

APR - 8 2011

Re: K110920
Trade/Device Name: Fukuda Denshi Diagnostic Ultrasound System UF-760AG
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: March 31, 2011
Received: April 1, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Fukuda Denshi Diagnostic Ultrasound System UF-760AG, as described in your premarket notification:

Transducer Model Number

FUT-SA162-5P
FUT-3-8 PA
FUT-3-8TEM
FUT-LA385-12P
FUT-5-12L50
FUT-CA602-5P
FUT-CVA403-6A
FUT-TVG114-7A
FUT-PEN2

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Fukuda Denshi Co, Ltd
39-4 Hongo 3-chome,
Bunkyo-ku, Tokyo, Japan

FUKUDA DENSHI

Indications For Use Form

510(k) Number (If known)

Device Name: Fukuda Denshi Diagnostic Ultrasound System UF-760AG

Indications for Use:

The system is intended for use by a qualified physician for diagnostic ultrasound imaging or fluid flow analysis of the human body in Fetal/Obstetric, Gynecological, Abdominal (renal, Gyn/Pelvic), Small Organ (thyroid, breast, testes, etc.), Adult Cephalic, Trans-vaginal, Trans-cranial, Musculoskeletal (conventional & superficial), Cardiac-Adult/Pediatric/Fetal, Transesophageal (Cardiac), Peripheral vascular.

The UF-760AG ultrasound instrument is intended to perform the following diagnostic ultrasound investigations: Imaging (B-mode, 3D/4D, harmonic imaging), Time motion (M-mode), Pulsed wave Doppler (PW Doppler), Continuous wave Doppler (CW Doppler), Power Doppler, Doppler Tissue Imaging, Color Flow Mapping (CFM) and Color Time Motion (CM)

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920

Fukuda Denshi Co, Ltd
39-4 Hongo 3-chome,
Bunkyo-ku, Tokyo, Japan

FUKUDA DENSHI

Diagnostic Ultrasound Indications for Use Form

System: UF-760AG diagnostic ultrasound system

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined[1]	Other (specify)
Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	[3],[4],[5],[7]
	Abdominal	P	P	P		P	P	[3],[4],[5],[7]
	Intraoperative (specify)							
	Intraoperative (Neurological)							
	Laparascopic							
	Pediatric							
	Small organs[2]	P	P	P	P	P	P	[3],[5],[7]
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	[3],[5],[7]
	Transrectal							
	Transvaginal	P	P	P	P	P	P	[3],[5],[7]
	Transurethral							
	Transesophageal (non Card.)							
	Musculo-skeletal Conventional	P	P	P	P	P	P	[3],[5],[7]
	Musculo-skeletal Superficial	P	P	P	P	P	P	[3],[5],[7]
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	[3],[5],[6],[7]
	Cardiac Pediatric	P	P	P	P	P	P	[3],[6]
	Intravascular (Cardiac)							
	Transesophageal (Cardiac)	P	P	P	P	P	P	[6]
	Intra-cardiac							
	Other (specify)	P	P	P	P	P	P	
Peripheral Vessel		P	P	P	P	P	P	[3],[4],[5],[7]
Other (specify)								

N= new indication; P= previously cleared by FDA (K081919); E= added under this appendix

Notes:

[1] Combined modes are B+M, B+PWD (or CWD), B+Color, B+Color+M, B+Color+PWD (or CWD)
[2] Small organs includes thyroid, breast and testicle
[3] Harmonic Imaging
[4] 3D/4D
[5] Power Doppler
[6] Doppler Tissue Imaging
[7] Imaging for guidance of biopsy

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

Fukuda Denshi Co, Ltd
39-4 Hongo 3-chome,
Bunkyo-ku, Tokyo, Japan

FUKUDA DENSHI

Diagnostic Ultrasound Indications for Use Form

System: UF-760AG

Transducer: FUT-SA162-5P

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined[1]	Other (specify)
Ophthalmic								
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neurological)							
	Laparascopic							
	Pediatric							
	Small organs[2]							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	[3],[5],[7]
	Transrectal							
	Transvaginal							
	Transurethral							
	Transesophageal (non Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	[3],[6],[7]
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Transesophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel		P	P	P	P	P	P	[3],[5],[7]
Other (specify)								

N= new indication; P= previously cleared by FDA (K081919); E= added under this appendix

Notes:

[1] Combined modes are B+M, B+PWD (or CWD), B+Color, B+Color+M, B+Color+PWD (or CWD)
[2] Small organs includes thyroid, breast and testicle
[3] Harmonic Imaging
[5] Power Doppler
[6] Doppler Tissue Imaging
[7] Imaging for guidance of biopsy

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

Fukuda Denshi Co, Ltd
39-4 Hongo 3-chome,
Bunkyo-ku, Tokyo, Japan

FUKUDA DENSHI

Diagnostic Ultrasound Indications for Use Form

System: UF-760AG

Transducer: FUT-3-8 PA

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined[1]	Other (specify)
Ophthalmic								
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neurological)							
	Laparascopic							
	Pediatric							
	Small organs[2]							
	Neonatal Cephalic							
	Adult Cephalic							
	Transrectal							
	Transvaginal							
	Transurethral							
	Transesophageal (non Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	P	P	P	P	[3],[6]
	Intravascular (Cardiac)							
	Transesophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel								
Other (specify)								

N= new indication; P= previously cleared by FDA (K081919); E= added under this appendix

Notes:

[1] Combined modes are B+M, B+PWD (or CWD), B+Color, B+Color+M, B+Color+PWD (or CWD)

[2] Small organs includes thyroid, breast and testicle

[3] Harmonic Imaging

[6] Doppler Tissue Imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920

Fukuda Denshi Co, Ltd
39-4 Hongo 3-chome,
Bunkyo-ku, Tokyo, Japan

FUKUDA DENSHI

Diagnostic Ultrasound Indications for Use Form

System: UF-760AG

Transducer: FUT-3-8TEM

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined[1]	Other (specify)
Ophthalmic								
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neurological)							
	Laparascopic							
	Pediatric							
	Small organs[2]							
	Neonatal Cephalic							
	Adult Cephalic							
	Transrectal							
	Transvaginal							
	Transurethral							
	Transesophageal (non Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Transesophageal (Cardiac)	P	P	P	P	P	P	[6]
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel								
Other (specify)								

N= new indication; P= previously cleared by FDA (K081919); E= added under this appendix

Notes:

[1] Combined modes are B+M, B+PWD (or CWD), B+Color, B+Color+M, B+Color+PWD (or CWD)

[2] Small organs includes thyroid, breast and testicle

[6] Doppler Tissue Imaging

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD) Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920

Diagnostic Ultrasound Indications for Use Form

System: UF-760AG

Transducer: FUT-LA385-12P

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined[1]	Other (specify)
Ophthalmic								
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neurological)							
	Laparascopic							
	Pediatric							
	Small organs[2]	P	P	P	P	P	P	[3],[5],[7]
	Neonatal Cephalic							
	Adult Cephalic							
	Transrectal							
	Transvaginal							
	Transurethral							
	Transesophageal (non Card.)							
	Musculo-skeletal Conventional	P	P	P	P	P	P	[3],[5],[7]
	Musculo-skeletal Superficial	P	P	P	P	P	P	[3],[5],[7]
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Transesophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel		P	P	P	P	P	P	[3],[5],[7]
Other (specify)								

N= new indication; P= previously cleared by FDA (K081919); E= added under this appendix

Notes:

[1] Combined modes are B+M, B+PWD (or CWD), B+Color, B+Color+M, B+Color+PWD (or CWD)

[2] Small organs includes thyroid, breast and testicle

[3] Harmonic Imaging

[5] Power Doppler

[7] Imaging for guidance of biopsy

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) — Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920

Fukuda Denshi Co, Ltd
39-4 Hongo 3-chome,
Bunkyo-ku, Tokyo, Japan

FUKUDA DENSHI

Diagnostic Ultrasound Indications for Use Form

System: UF-760AG

Transducer: FUT-5-12L50

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined[1]	Other (specify)
Ophthalmic								
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neurological)							
	Laparascopic							
	Pediatric							
	Small organs[2]	P	P	P	P	P	P	[3],[5],[7]
	Neonatal Cephalic							
	Adult Cephalic							
	Transrectal							
	Transvaginal							
	Transurethral							
	Transesophageal (non Card.)							
	Musculo-skeletal Conventional	P	P	P	P	P	P	[3],[5],[7]
	Musculo-skeletal Superficial	P	P	P	P	P	P	[3],[5],[7]
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Transesophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel		P	P	P	P	P	P	[3],[5],[7]
Other (specify)								

N= new indication; P= previously cleared by FDA (K081919); E= added under this appendix

Notes:

[1] Combined modes are B+M, B+PWD (or CWD), B+Color, B+Color+M, B+Color+PWD (or CWD)

[2] Small organs includes thyroid, breast and testicle

[3] Harmonic Imaging

[5] Power Doppler

[7] Imaging for guidance of biopsy

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) (Division Sign-Off) (Per 21 CFR 801.109)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920

Fukuda Denshi Co, Ltd
39-4 Hongo 3-chome,
Bunkyo-ku, Tokyo, Japan

FUKUDA DENSHI

Diagnostic Ultrasound Indications for Use Form

System: UF-760AG

Transducer: FUT-CA602-5P

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined[1]	Other (specify)
Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	[3],[5],[7]
	Abdominal	P	P	P	P	P	P	[3],[5],[7]
	Intraoperative (specify)							
	Intraoperative (Neurological)							
	Laparascopic							
	Pediatric							
	Small organs[2]							
	Neonatal Cephalic							
	Adult Cephalic							
	Transrectal							
	Transvaginal							
	Transurethral							
	Transesophageal (non Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Transesophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel		P	P	P	P	P	P	[3],[5],[7]
Other (specify)								

N= new indication; P= previously cleared by FDA (K081919); E= added under this appendix

Notes:

[1] Combined modes are B+M, B+PWD (or CWD), B+Color, B+Color+M, B+Color+PWD (or CWD)

[2] Small organs includes thyroid, breast and testicle

[3] Harmonic Imaging

[5] Power Doppler

[7] Imaging for guidance of biopsy

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) (Division Sign-Off) Prescription Use (Per 21 CFR 801.109)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920

Diagnostic Ultrasound Indications for Use Form

System: UF-760AG

Transducer: FUT-CVA403-6A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined[1]	Other (specify)
Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N	N	N	N	[3],[4],[5]
	Abdominal	N	N	N	N	N	N	[3],[4],[5]
	Intraoperative (specify)							
	Intraoperative (Neurological)							
	Laparascopic							
	Pediatric							
	Small organs[2]							
	Neonatal Cephalic							
	Adult Cephalic							
	Transrectal							
	Transvaginal							
	Transurethral							
	Transesophageal (non Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Transesophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel		N	N	N	N	N	N	[3],[4],[5]
Other (specify)								

N= new indication; P= previously cleared by FDA (K081919); E= added under this appendix

Notes:

[1] Combined modes are B+M, B+PWD (or CWD), B+Color, B+Color+M, B+Color+PWD (or CWD)

[2] Small organs includes thyroid, breast and testicle

[3] Harmonic Imaging

[4] 3D/4D

[5] Power Doppler

Concurrence of CDRH, Office of Device Evaluation (ODE) — Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920

Fukuda Denshi Co, Ltd
39-4 Hongo 3-chome,
Bunkyo-ku, Tokyo, Japan

FUKUDA DENSHI

Diagnostic Ultrasound Indications for Use Form

System: UF-760AG

Transducer: FUT-TVG114-7A

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined[1]	Other (specify)
Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	[3],[5],[7]
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neurological)							
	Laparascopic							
	Pediatric							
	Small organs[2]							
	Neonatal Cephalic							
	Adult Cephalic							
	Transrectal							
	Transvaginal	P	P	P	P	P	P	[3],[5],[7]
	Transurethral							
	Transesophageal (non Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Transesophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel								
Other (specify)								

N= new indication; P= previously cleared by FDA (K081919); E= added under this appendix

Notes:

[1] Combined modes are B+M, B+PWD (or CWD), B+Color, B+Color+M, B+Color+PWD (or CWD)

[2] Small organs includes thyroid, breast and testicle

[3] Harmonic Imaging

[5] Power Doppler

[7] Imaging for guidance of biopsy

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) — Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920

Fukuda Denshi Co, Ltd
39-4 Hongo 3-chome,
Bunkyo-ku, Tokyo, Japan

FUKUDA DENSHI

Diagnostic Ultrasound Indications for Use Form

System: UF-760AG

Transducer: FUT-PEN2

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
		B	M	PWD	CWD	Color Doppler	Combined[1]	Other (specify)
Ophthalmic								
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neurological)							
	Laparascopic							
	Pediatric							
	Small organs[2]							
	Neonatal Cephalic							
	Adult Cephalic							
	Transrectal							
	Transvaginal							
	Transurethral							
	Transesophageal (non Card.)							
	Musculo-skeletal Conventional							
	Musculo-skeletal Superficial							
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult			P	P			
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Transesophageal (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel								
Other (specify)								

N= new indication; P= previously cleared by FDA (K081919); E= added under this appendix

Notes:

[1] Combined modes are B+M, B+PWD (or CWD), B+Color, B+Color+M, B+Color+PWD (or CWD)

[2] Small organs includes thyroid, breast and testicle

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD) — Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110920